REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated December 1, 2005.

Status of the Claims

Claims 42-43, 62-63, 65, 73 and new claims 91-93 are pending in the application. Claims 1-41, 44-61, 64, 66-72 and 74-90, which are withdrawn from consideration, have been canceled without prejudice to further prosecution. Claims 42, 43, 62, 63, 65 and 73 have been amended in order to more particularly point out and distinctly claim that which Applicants regard as the invention. New claims 91-93 are presented. Support for the newly presented and amended claims can be found generally through Applicants' specification.

Claim Objections

Claims 42, 62-63, 65 and 73 are objected to because they recite non-elected subject matter. Applicants have above amended claims 42, 62 and 73 to remove recitation of or reference to non-elected subject matter and request that the claim objections be withdrawn

Claim Rejections - 35 USC §101

Applicants appreciate and accept the Examiner's acknowledgement of the utility of the sHIgM22 antibody. Claims 42-43, 62-63, 65 and 73 are rejected under 35 U.S.C. 101 as directed to non-statutory subject matter, encompassing a product of nature. Applicants have above amended claims 42, 43, 62, 63, 65 and 73 to add the term "isolated". Applicants request the 35 U.S.C. 101 rejection be withdrawn.

Claim Rejections - 35 USC §112, First Paragraph

The Examiner has rejected claims 42, 62-63, 65 and 73 under 35 U.S.C. 112, first paragraph, because the Examiner asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most connected, to make and use the invention commensurate in scope with these claims. The Examiner remarks that the Specification enables pharmaceutical compositions of monoclonal antibody SHIgM22, but does not provide

enablement for compositions comprising all active fragments, binding partners and antibodies derived therefrom. The Examiner cites the Wands factors and asserts that the practice of the claims requires undue experimentation. The Examiner further asserts that the Specification fails to disclose any recombinant antibodies derived from sHIgM22. Applicants respectfully disagree. While some experimentation to make and test the antibodies, monomers and fragments as claimed would be necessary, such experimentation would utilize well known and standard skills and would not constitute undue experimentation. The Specification enables antibodies and compositions mAb sHIgM22 (LYM 22), monomers thereof, active fragments thereof, and recombinant antibodies derived therefrom. The claims as presented reasonably include fragments which are capable of binding oligodendrocytes, a capacity and activity which can readily be assayed and determined. The Specification provides ample teaching, in addition to the knowledge and significant skill of the skilled artisan, and describes monomers, active fragments and recombinant antibodies. In fact, the Specification including in Example 9 and Example 20, details the construction and expression of recombinant sHIgM22 (22BII) and demonstrates its activity (particularly at page 187). Studies with recombinant sHIgM22 are also described in Example 18. The generation of recombinant IgG subtype G1 and G2 recombinant Lym22 (sHIgM22) is detailed in Example 21. IgM monomers capable of inducing remyelination are described in Example 12, as well as $(Fab')_2$ fragments of sHIgM22. Lym22 Fv, F(ab) and $F(ab')_2$ fragments and monomers are described and tested in Example 23. Thus, the Specification provides a remarkable amount of teaching and support for each and any of the claimed sHIgM22 antibody, monomers thereof, active fragments thereof, and recombinant antibodies derived therefrom. Contrary to the Examiner's assertion Applicants submit that the claims as presented are enabled and it would not constitute undue experimentation for the skilled artisan to make and use the invention as claimed.

The Examiner further remarks at paragraph 14 that he rejects claims 42-43, 62-63, 65 and 73 as not having been described so as to enable one to make and/or use the invention, the Examiner having determined that in order for the skilled artisan to make the claimed antibodies, the artisan must have access to the hybridoma that produces the antibodies. Applicants respectfully disagree. The antibody sHIgM 22, its activity, its capacity, and exemplary sequences are described and detailed in the specification. The skilled artisan is clearly enabled to

make and/or use the invention, without the need or requirement for access to the hybridoma that produces the antibody.

The Examiner has rejected claims 42, 62-63, 65 and 73 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully disagree and would assert that the claims as presented meet the written description requirements. The Specification, as noted above, describes each of sHIgM22 antibody, monomers thereof, active fragments thereof, and recombinant antibodies derived therefrom, disclosing a reasonable number of members and supporting the scope of the claimed genus.

In view of the foregoing remarks, Applicants submit that the Examiner's rejections under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

Claim Rejections - 35 USC § 112, Second Paragraph

The Examiner has rejected claims 62-65 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention.

The Examiner rejects claim 62 in that it refers to nucleic acid sequences. Applicants have above amended claim 62 to properly reference amino acid sequences and submit that the claim as amended is clear.

The Examiner rejects claim 65 in the recitation of the term "chimeric (bi-specific)", implying that the two terms are identical and interchangeable. Applicants have above amended claim 65 to clarify the language to cover bispecific (antibody that binds two antigens) and chimeric (antibody comprised of antibody fragments from two different species) antibodies. Chimeric (mouse/human) antibody 94.03 and sHIgM22 are described and provided in the Specification at Example 9, including at pages 187-191. Bispecific antibody having a plurality of antibody combining sites, each immunospecific for a different antigen, is defined in the Specification at page 52.

Applicants request that the Examiner's 35 U.S.C. 112, second paragraph, rejection be withdrawn.

Claim Rejections - 35 USC §102

Claims 42, 62-63, 65 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Alberts et al, 1994 [Molecular Biology of the Cell, pp. 187-188, 1206-1216], as evidenced by Queen [U.S. Patent 5,693,762, issued December 2, 1997, earliest effective filing date December 28, 1988]. The Examiner remarks that the instant claims include "active fragments" of antibodies and Alberts teaches Fc fragments and teaches monoclonal antibodies. Queen teaches chimeric antibodies comprised of regions of two different antibodies which combine to form an intact antibody, thus providing, the Examiner asserts, evidence that the active fragments taught by Alberts apply to chimeric antibodies. The Examiner takes the position that claim 73 is a product-by-process claim sufficiently broad to encompass Fc fragments per se and it is therefore rejected as well. Applicants respectfully disagree and submit that Alberts et al, as evidenced by Queen et al, does not anticipate the claimed compositions and antibodies. Anticipation is a question of fact and the cited reference and evidence reference do not teach or describe the specific sHIgM22 antibody or active fragments thereof. The Examiner implies that any antibody fragment per se anticipates an antibody fragment of the specific sHIgM22 antibody. Applicants have above amended claims 42, 62-63, 65 and 73 and submit that the above claim amendments and claim clarifications serve to further obviate the 35 U.S.C. 102 rejection.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's 35 U.S.C. 102 rejection is obviated and should be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,
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